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REMARKS

The Applicant would like to draw the Examiner's attention to a new book that was recently published. The book was released after June 7, 2004 and is entitled "Handbook of Local Anesthesia" by Dr. Stanley Malamed (Fifth edition). It is the Applicant's (who is dentist himself) belief that this textbook on local anesthesia is the standard training textbook in this country and the best selling textbook on the subject in the world. Its author, Dr. Malamud, is the Professor of Anesthesia and Medicine at University of Southern California, School of Medicine and is regarded as an international leader in the field today.

Attached hereto as Exhibit C are the front pages of the book and pages 99-107. On pages 101-102 there is a discussion about the problems associated with bending needles during anesthesia. This discussion is then followed immediately by a discussion of Dr. Hochman's bi-rotational insertion technique (BRIT). The discussion concludes with the statement "The BRIT, or birotational insertion technique, is simple and easy and has been demonstrated to improve injection techniques because the deflection of a standard needle during insertion is minimized."

Clearly, this book represents a glowing endorsement of the subject invention, and further demonstrates that the invention is coming to be accepted as pioneering invention. Therefore it is respectfully submitted that the subject application is patentable over the prior art.

Respectfully submitted,

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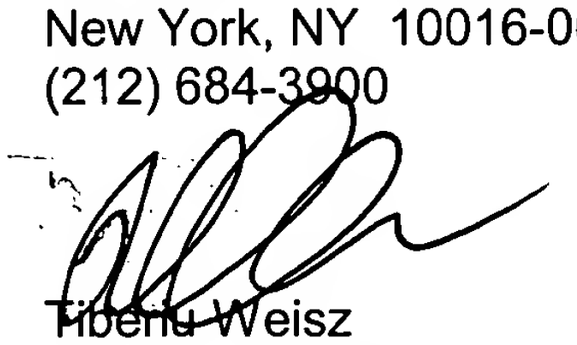

Tiberiu Weisz
Reg. No. 29,876

Enclosure: Exhibit C

ELSEVIER MOSBY

Handbook of

LOCAL ANESTHESIA

FIFTH EDITION

STANLEY F. MALAMED

Handbook of

LOCAL ANESTHESIA

FIFTH EDITION

Stanley F. Malamed, DDS

Professor of Anesthesia and Medicine
School of Dentistry
University of Southern California
Los Angeles, California

With 400 illustrations

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CHAPTER 6

The Needle

TYPES

The needle permits the local anesthetic solution to travel from the dental cartridge into the tissues surrounding the needle tip. Most needles used in dentistry are stainless steel and are disposable. Other needles are constructed of platinum or an iridium-platinum or ruthenium-platinum alloy. The stainless steel needle is highly recommended. Needles currently available for dental practices are presterilized and disposable.

Reusable needles should not be used for injections.

Because the needle represents the most dangerous component of the armamentarium, the one most likely to produce injury to patient or doctor, "safety needles" are being developed.[1] Although these needles are not yet widely used in dentistry, it is probable that within the next decade their use will become commonplace.

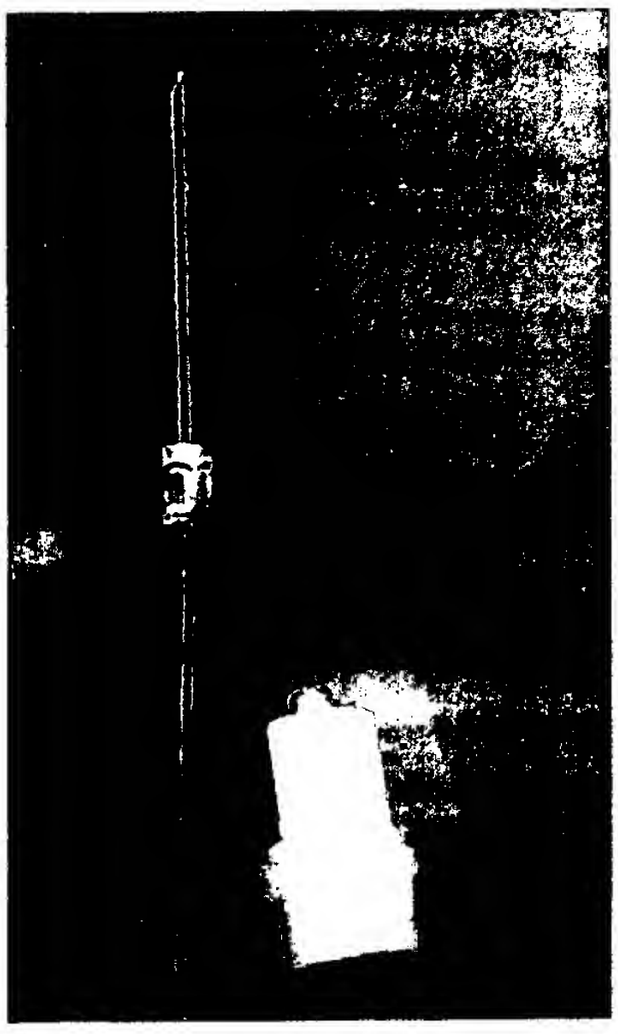

Figure 6-1. Metal disposable needle, dissembled.

PARTS

The needle is composed of a single piece of tubular metal around which is placed plastic or a metal syringe adaptor and the needle hub (Fig. 6-1).

All needles have the following components in common: the bevel, the shaft, the hub, and the cartridge-penetrating end (Fig. 6-2).

The *bevel* defines the point or tip of the needle. Bevels are described by manufacturers as long, medium, and short. Several authors have confirmed that the greater the angle of the bevel with the long axis of the needle, the greater will be the degree of deflection as the needle passes through hydrocolloid (or the soft tissues of the

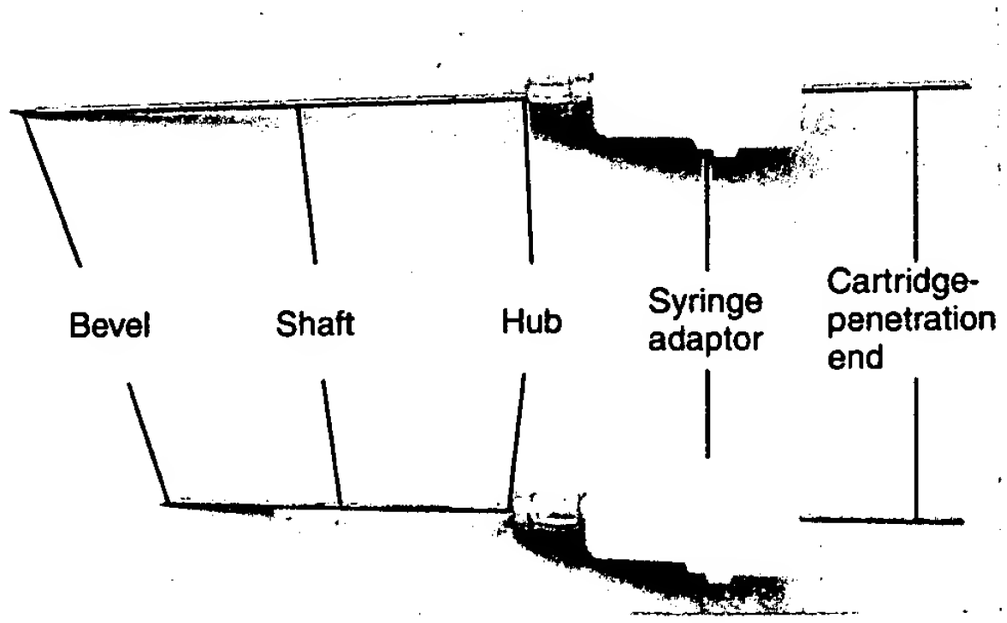

Figure 6-2. Components of dental local anesthetic needle. Long needle *(top)*; short needle *(bottom)*.

Figure 6-3. Radiograph demonstrating varying degrees of needle deflection with different gauges (left to right, 30, 27, and 25). (From Robison SE, et al: Comparative study of deflection characteristics and fragility of 25-, 27- and 30-gauge short dental needles, *J Am Dent Assoc* 109:920-924, 1984.)

mouth) (Fig. 6-3).[2-4] A needle whose point is centered on the long axis (e.g., the Huber point and the Truject needle; Fig. 6-4) will deflect less than a beveled-point needle whose point is eccentric (Fig. 6-5; Table 6-1).

Several manufacturers of dental needles have placed indicators on the plastic or metal hub to help orient the doctor to the position of the bevel.

The *shaft* of the needle is one long piece of tubular metal running from the tip of the needle, through the hub, and continuing to the piece that penetrates the cartridge (see Fig. 6-1). Two factors to be considered about this component of the needle are the diameter of its lumen (e.g., the needle gauge) and the length of the shaft from point to hub.

The *hub* is a plastic or metal piece through which the needle attaches to the syringe. The interior surface of the *plastic syringe adaptor* of the needle is not prethreaded; therefore to attach a plastic-hubbed needle to a syringe, the needle must be pushed toward the syringe while it is being attached. Metallic-hubbed needles are prethreaded.

The *cartridge-penetrating end* of the dental needle extends through the needle adaptor and perforates the diaphragm of the local anesthetic cartridge. Its tip rests within the cartridge.

When needles are selected for use in various injection techniques, the two factors that must be considered are the *gauge* and the *length*.

GAUGE

Gauge refers to the diameter of the lumen of the needle: the smaller the number, the greater the diameter of the lumen. A 30-gauge needle has a smaller internal diameter than a 25-gauge needle. In the United States, needles are color-coded by gauge (Fig. 6-6).

There is a growing trend toward the use of smaller-diameter (higher number gauge) needles, based on the assumption that they are less traumatic to the patient than needles with larger diameters (Table 6-2). This assumption is unwarranted.[5] Hamburg[6] demonstrated in 1972 that patients cannot differentiate among 23-, 25-, 27-, and 30-gauge needles. A clinical experiment proves this point:

1. Several needles—25-, 27-, and 30-gauge—should be selected.
2. The buccal mucosa over the maxillary anterior teeth should be dried.
3. No topical anesthetic should be used.
4. The mucosa should be taut.
5. The mucosa should be gently penetrated (about 2 to 3 mm) with each needle without revealing to the patient which needle is being used. A different site should be selected for each penetration.
6. The patient should be questioned about the needles: Which was felt the most? Which the least?

In hundreds of clinical demonstrations, no patient could correctly determine the gauge of each needle. The usual response has been that he or she could not discern any difference.

Larger-gauge needles (e.g., 25-gauge) have distinct advantages over smaller ones (Box 6-1): *Less deflection* occurs as the needle passes through tissues (see Table 6-1 and Fig. 6-3). This leads to *greater accuracy* in needle

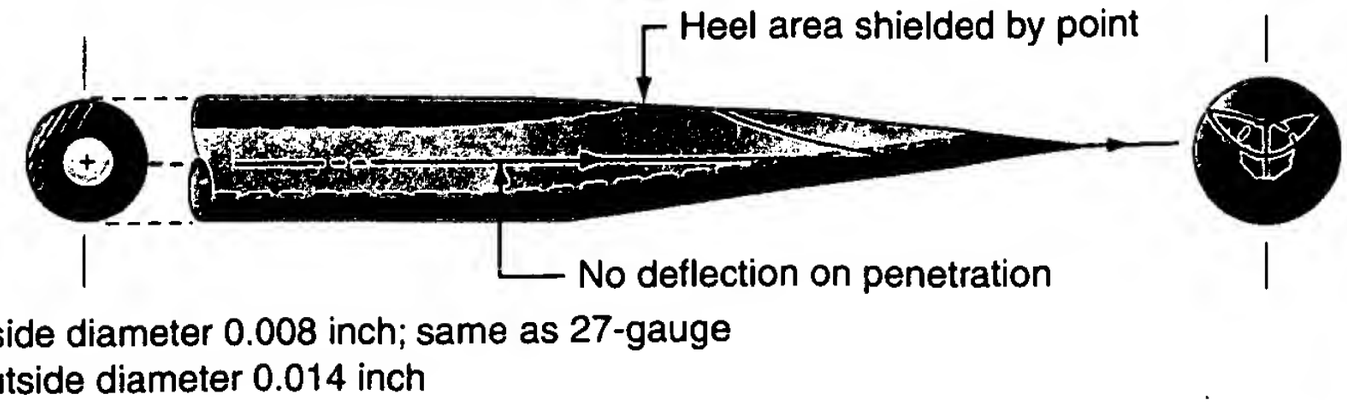

Figure 6-4. The tip of a nondeflecting needle is located in the center of the shaft, thereby minimizing deflection as the needle penetrates soft tissues.

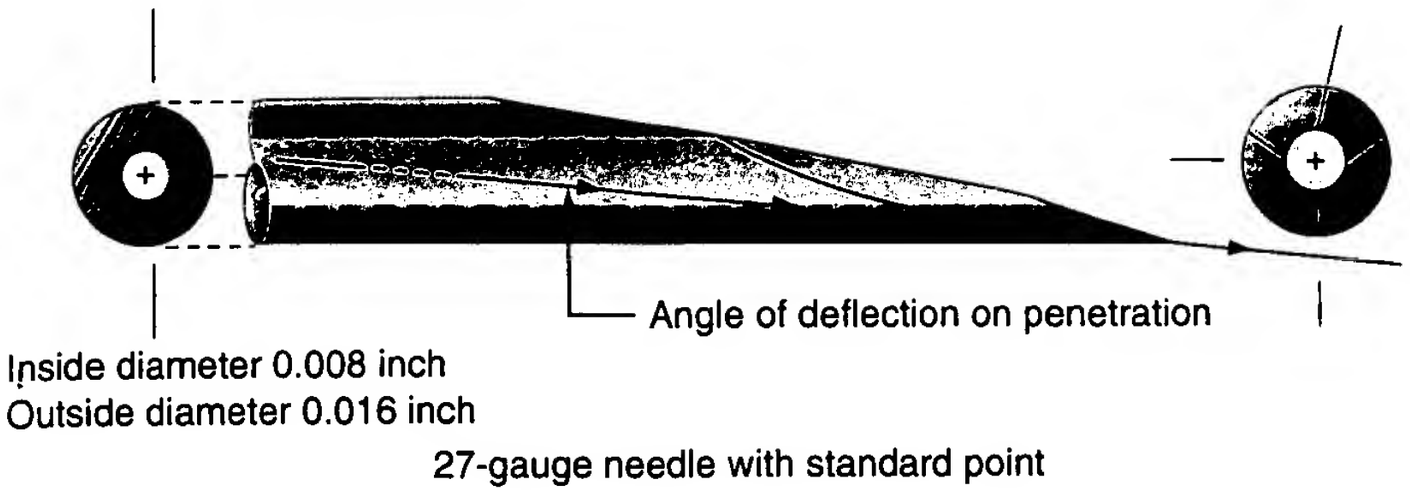

Figure 6-5. Conventional dental needle. The needle tip lies at the lower edge of the needle shaft, thereby producing deflection as the needle passes through soft tissue.

insertion and, hopefully, to increased success rates, especially for techniques in which the depth of soft tissue being penetrated is significant (e.g., the inferior alveolar, Gow-Gates mandibular, Akinosi-Vazirani mandibular, and ASA [infraorbital] nerve blocks). Needle breakage, although not common with disposable needles, is much less likely to occur with a larger needle. Numerous authors[7–10] have stated that aspiration of blood is easier and more reliable through a larger lumen. Foldes and McNall[7] reported the following findings based on an unpublished study by Monheim:

1. One hundred percent positive aspirations were achieved from blood vessels with 25-gauge needles.
2. Eighty-seven percent positive aspirations were achieved from blood vessels with 27-gauge needles.
3. Two percent positive aspirations were achieved from blood vessels with 30-gauge needles.

Trapp and Davies,[11] however, reported that in vivo human blood may be aspirated through 23-, 25-, 27-, and 30-gauge needles without a clinically significant difference in resistance to flow.

Despite this ambiguity concerning ability to aspirate blood through various-gauge needles, the use of larger needles (e.g., 25-gauge) is recommended for any injection technique used in a highly vascular area or when needle deflection through soft tissue would be a factor. Although blood may be aspirated through all 23- through 30-gauge needles, more pressure is necessary to aspirate when smaller-gauge needles are used, increasing the likelihood that the harpoon will become dislodged from the rubber plunger during aspiration.

Industry standards for needle gauge have been in place for years (Table 6-3), yet Wittrock and Fischer[12] showed in 1968 that variations in internal diameter do exist, and 35 years later such differences are still encountered. Larger-gauge needles (e.g., 25-gauge) should be used when there is a greater risk of positive aspiration, as during an inferior alveolar, posterior superior alveolar, or mental or incisive nerve block.

The most commonly used (e.g., most purchased) needles in dentistry are the 27-gauge long, and the 30-gauge short.[13] The 25-gauge, however, is the preferred needle for all injections presenting a high risk of positive aspiration. The 27-gauge can be used for all other injection techniques, provided the aspiration percentage is low and tissue penetration depth is not great (increased deflection). The 30-gauge needle is not specifically recommended for any injection, although it may be used in instances of local infiltration, as when obtaining hemostasis during periodontal therapy.

TABLE 6-1
Deflection of Needles Inserted in Hydrocolloid Tubes to Their Hubs

Needle Type	Length (mm, Tip to Hub)	Maximum Tip Deflection (mm, ± SD)
25-Gauge long (conventional)	35	7.1 ± 0.81*
27-Gauge long (conventional)	36	8.4 ± 1.2*
27-Gauge short (conventional)	26	4.6 ± 0.97†
28-Gauge long (nondeflecting)	31	1.1 ± 0.82
28-Gauge short (nondeflecting)	22	0.8 ± 0.91

Data modified from Jeske AH, Boshart BF: Deflection of conventional versus non-deflecting dental needles in vitro, *Anesth Prog* 32:62-64, 1985.

*A statistically significant difference from the nondeflecting long needle ($p < 0.01$); n = 10 needles in each group.

†A statistically significant difference from the nondeflecting short needle ($p < 0.01$); n = 10 needles in each group.

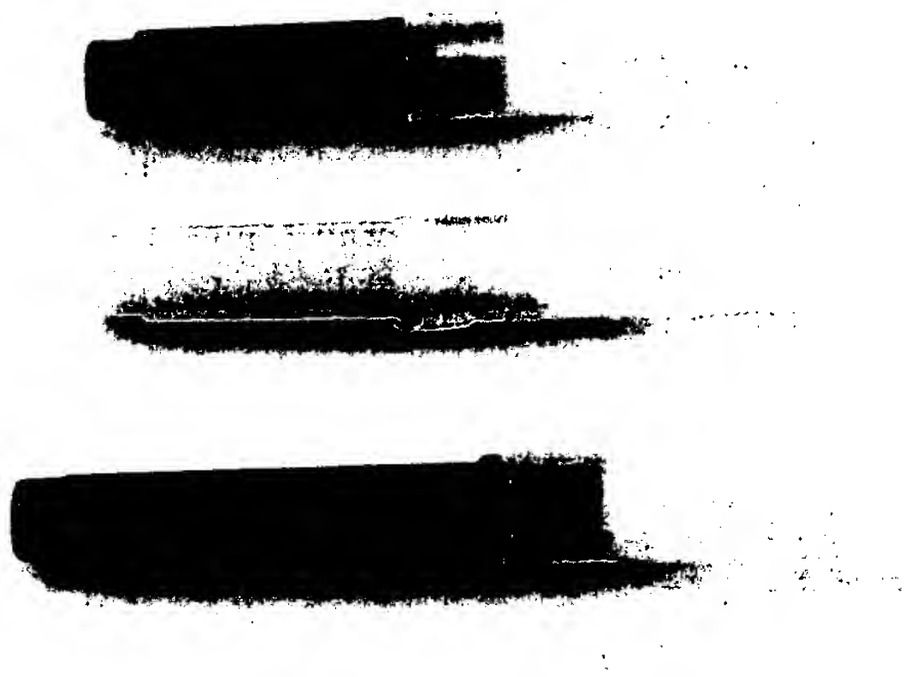

Figure 6-6. Color-coding by needle gauge: 25-gauge, red; 27-gauge, yellow; 30-gauge, blue.

TABLE 6-2
Needle Gauges Used in Practice

Gauge	Inferior Alveolar Nerve Block (%)	Maxillary Infiltration (%)
23	1.1	0.0
25	66.9	19.1
27	32.0	60.1
30	0.0	20.8

Deflection becomes important when a needle must penetrate a greater thickness of soft tissue. On the standard dental needle (see Fig. 6-5), the tip of the point is located eccentrically. As the needle penetrates soft tissue, the point of the needle is deflected by the tissue through which it passes. The greater the angle of the bevel, the greater is the degree of needle deflection. Every decade or so a needle is introduced on which the tip of the point is located in the center of the lumen, thereby minimizing deflection as the needle passes through soft tissue (see Fig. 6-4). Jeske and Boshart[2] demonstrated the effectiveness of this "nondeflecting" needle (see Table 6-1). However, it needs to be shown clinically that a lesser degree of needle deflection occurring as the needle passes through soft tissues actually results in an increased rate of successful anesthesia compared with that observed with standard needles. Over years of use, dentists become accustomed to the deflecting needles they use and, over time, modify their injection techniques to accommodate this deflection. Change to a nondeflecting needle might initially lead to lower success rates.

Minimizing Needle Deflection: Rotational Insertion Technique

A new approach to reducing needle deflection has been described. The technique of rotational insertion (described as bi-rotational insertion technique [BRIT]), a technique in which the operator rotates the handpiece or needle in a back-and-forth rotational movement while advancing the needle through tissues, is similar to techniques used for acupuncture or endodontic instrumentation. Hochman and Friedman demonstrated that needle deflection could be virtually eliminated by using a rotational insertion technique during needle movement.[14] An in vitro study of 60 needle insertions was performed into a tissuelike medium with three different needle gauges comparing

BOX 6-1

Advantages of Larger-Gauge Needles Over Smaller-Gauge Needles

1. Less deflection as needle advances through tissues
2. Greater accuracy in injection
3. Less chance of needle breakage
4. Easier aspiration
5. No perceptual difference in patient comfort

TABLE 6-3
Specifications for Needle Gauges

Gauge	Outer Diameter [mm]	Inner Diameter [mm]
7	4.57	3.81
8	4.19	3.43
10	3.40	2.69
11	3.05	2.39
12	2.77	2.16
13	2.41	1.80
14	2.11	1.60
15	1.83	1.32
16	1.65	1.19
17	1.50	1.04
18	1.27	0.84
19	1.07	0.69
20	0.91	0.58
21	0.81	0.51
22	0.71	0.41
23	0.64	0.33
25	0.51	0.25
26	0.46	0.25
27	0.41	0.20
30	0.31	0.15

Dental needle gauges highlighted.

rotational insertion to the traditional linear nonrotating insertion technique. The study demonstrated that deflectional bending of a needle could be minimized or eliminated, regardless of the length or gauge of a needle, as long as the insertion was performed using the rotational insertion technique.

Deflection of a needle is a consequence of the resultant forces acting on the needle bevel during tissue penetration and advancement. An eccentric pointed beveled needle generates several different forces that act on it during insertion when a nonrotating linear insertion technique is used. A linear insertion technique is the conventional technique used with the traditional dental syringe that is typically held with a palm-thumb grasp (Fig. 6-7). During this type of insertion a force perpendicular to the forward directional movement (vector) acts on the surface of the

Figure 6-7. Traditional syringe held in palm-thumb grasp.

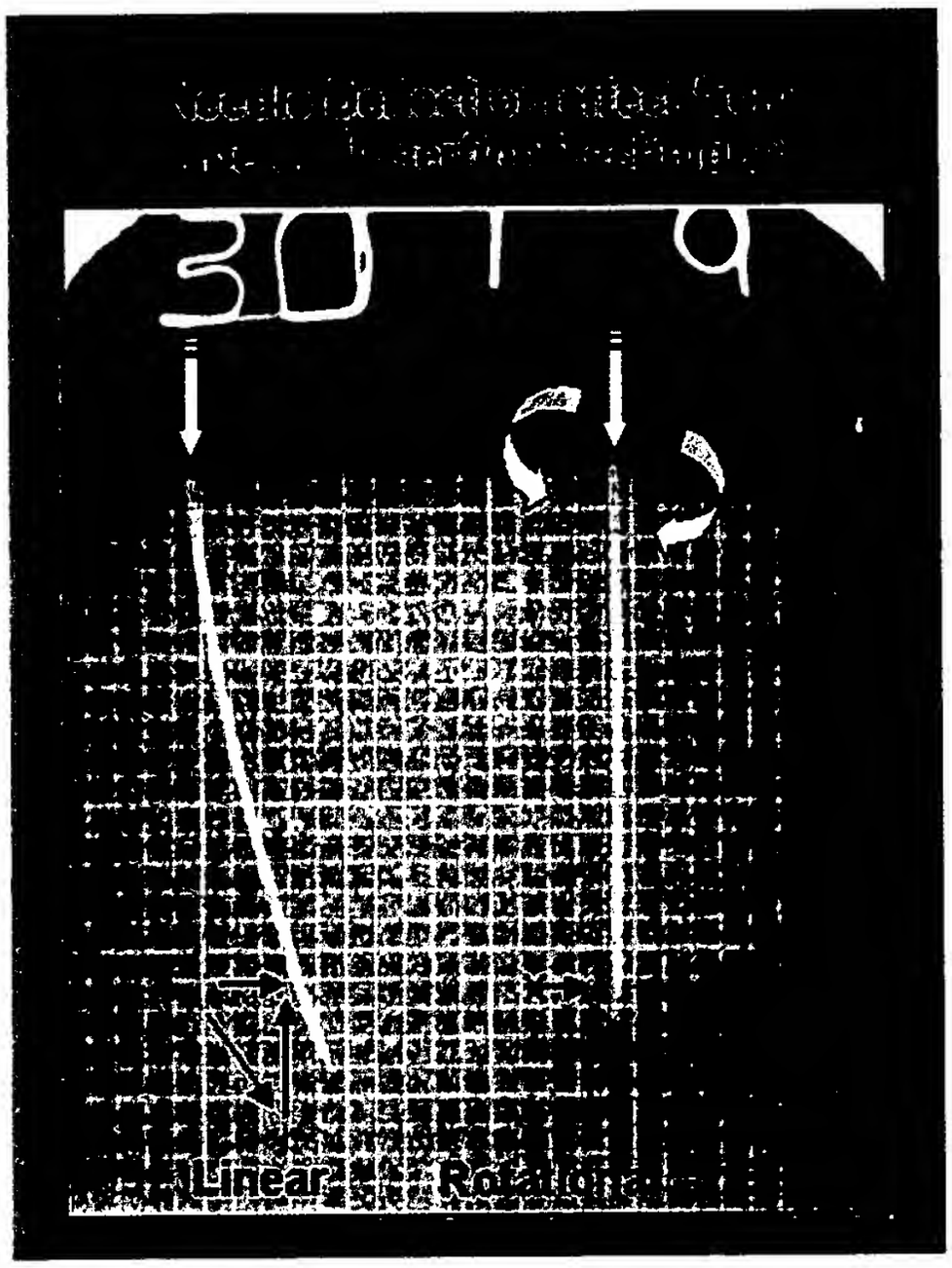

Figure 6-8. BRIT (birotational insertion technique).

beveled needle, causing the needle to bend or deflect in a direction opposite to which the bevel faces (e.g., if the bevel faces "up" the advancing movement causes a beveled needle to deflect "downward"). The longer the needle length, the more exaggerated bending or deflection becomes as a result of the greater distance traveled along the deflecting path. The smaller the diameter of the needle, the more exaggerated the bending or deflecting because a smaller-gauge needle is less capable of resisting the deflection or bending force on the surface of the beveled needle tip.

When the BRIT is used during needle insertion the perpendicular force that causes deflection is eliminated or "neutralized" from the constant changing of bevel orientation as it is rotated (Fig. 6-8).[14] This allows eccentrically beveled needles to travel in a straight path. The traditional handheld syringe requires a palm-thumb grasp (see Fig. 6-7) that does not permit such a technique. The CCLAD device *The Wand/CompuDent* (discussed in Chapter 5) employs a lightweight handpiece that is held with a "penlike" or "dart" grasp that is easily rotated.

A subsequent study by the same authors demonstrated that the BRIT has the added benefit of reducing the force necessary for needle penetration and advancement through tissues.[15] This is explained as follows. With rotational insertion, all resultant forces are directed toward the forward path of insertion since the deflecting or bending forces have been eliminated from the rotational insertion technique, as described in the preceding. This thereby allows forward movement of the needle to occur more efficiently and with less effort (e.g., less force). In addition, rotation of the beveled needle allows the sharp cutting edge to contact the full circumference of the tissue surface, contributing to the reduction of force that is necessary during penetration and advancement. This is not unlike the rotational effect that a surgical drill bit has as it is boring through tissue or bone.

The BRIT, or birotational insertion technique, is simple and easy and has been demonstrated to improve injection techniques because the deflection of a standard needle during insertion is minimized.[16]

LENGTH

Dental needles are available in two lengths: long and short. Ultrashort needles are also available with 30-gauge needles. Despite the claim for uniformity of length by manufacturers, significant differences are found (Table 6-4).

The *average* length of a short needle is 20 mm (measured hub to tip) and 32 mm for the long dental needle (Fig. 6-9).

Needles should not be inserted into tissues to their hubs unless it is absolutely necessary for the success of the injection.

One of reasons for this precaution is needle breakage, which, although rare, does occur. The weakest (most rigid part, receiving the greatest stress) portion of the needle is at the hub, which is where needle breakage

TABLE 6-4
Needle Lengths

Manufacturer	25-Gauge Long	25-Gauge Short	27-Gauge Long	27-Gauge Short	30-Gauge Long	30-Gauge Short	30-Gauge Ultrashort
Industry standard	32	20	32	20			
Manufacturer A	30		30	21	25	21	
Manufacturer B	32 ± 1.5	22 ± 1.5	32 ± 1.5	22 ± 1.5		21 ± 1.5	12 ± 1.0
Manufacturer C			32	21	25	21	
Manufacturer D	35		35	25		25	10
Manufacturer E	32			21		19	

All measurements obtained directly from needle manufacturers.

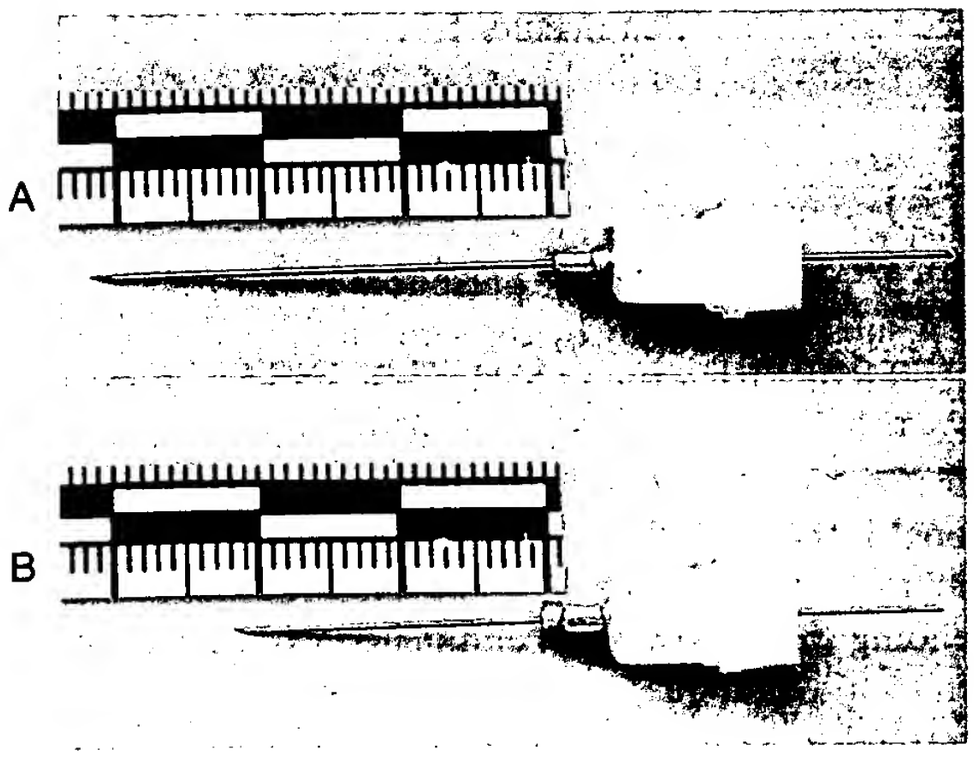

Figure 6-9. **A,** Long dental needle length approximately 32 mm. **B,** Short dental needle length approximately 20 mm.

happens. When a needle that is inserted into the soft tissues to its hub breaks, the elastic properties of the tissues permit them to rebound and cover (bury) the needle entirely. Retrieval usually is difficult (as discussed in Chapter 17). If even a small portion (5 mm or more) of the broken needle shaft remains visible within the oral cavity, it can be retrieved with a hemostat or pickup forceps.

A long needle is preferred for all injection techniques where the penetration of significant thicknesses of soft tissue (e.g., the inferior alveolar, Gow-Gates mandibular, Akinosi mandibular, infraorbital, and maxillary nerve blocks) is required. Short needles may be used for any injection in any patient who does not require the penetration of significant depths of soft tissue (e.g., close to or beyond 20 mm).

CARE AND HANDLING

Needles available to the dental profession today are presterilized and disposable. With proper care and handling, they should not be the cause of significant difficulties.

1. Needles must *never* be used on more than one patient.
2. Needles should be changed after several (three or four) tissue penetrations in the same patient.
   a. After three or four insertions, stainless steel disposable needles become dulled. Tissue penetration becomes more traumatic with each insertion, producing pain on insertion and soreness when sensation returns after the procedure.
3. Needles should be covered with a protective sheath when not being used to prevent accidental needle stick with a contaminated needle. (See the discussion in Chapter 9.)
4. Attention should always be paid to the position of the uncovered needle tip, whether inside or outside the patient's mouth. This minimizes the risk of potential injury to the patient and the administrator.

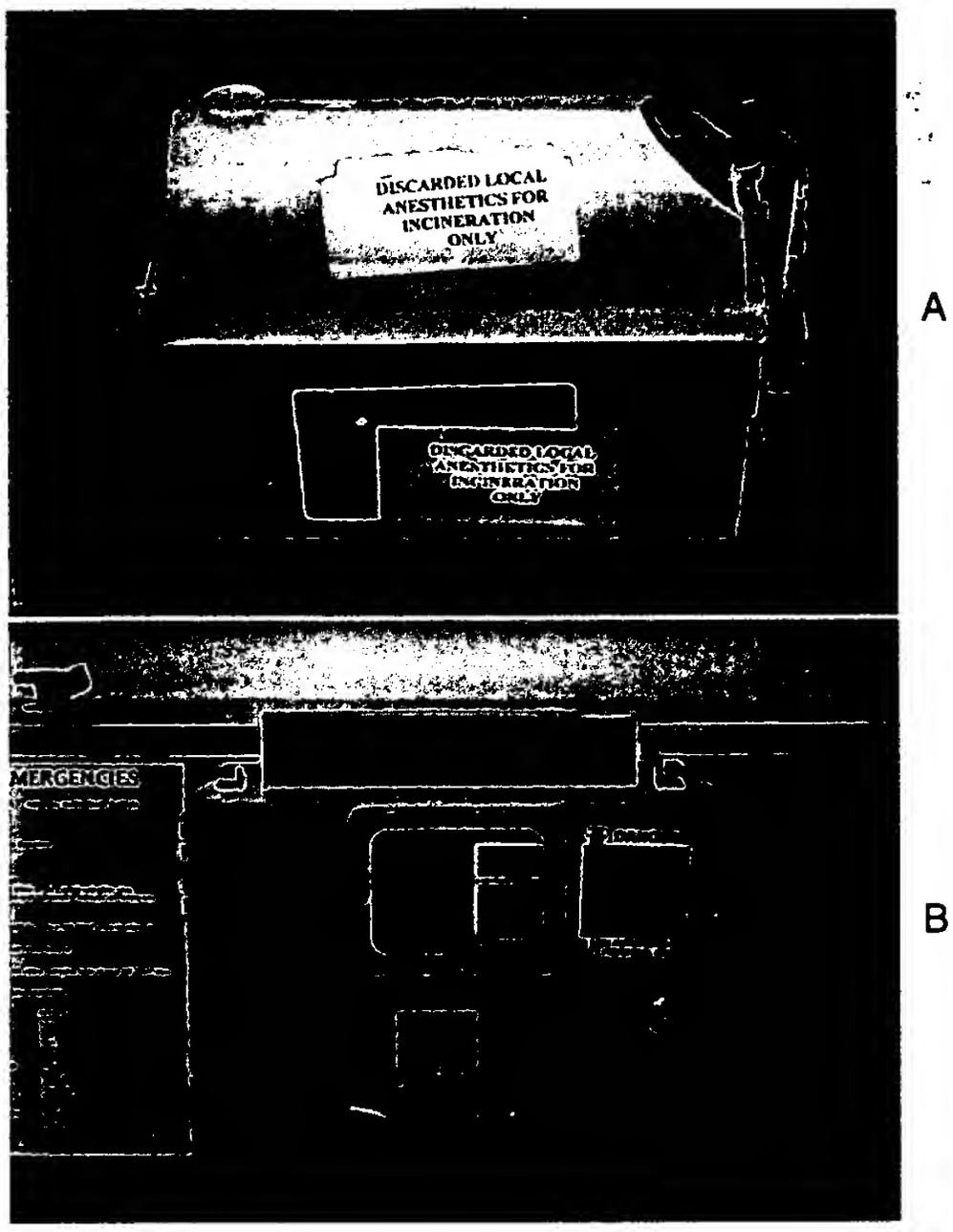

Figure 6-10. **A,** Container for disposal of discarded local anesthetic cartridges. **B,** "Sharps" container for disposing of contaminated needles.

5. Needles must be properly disposed of after use to prevent possible injury or reuse by unauthorized individuals. Needles can be destroyed in any of the following ways:
   a. Contaminated needles (as well as all other items contaminated with blood or saliva, such as cartridges) should be disposed of in special "contaminated" or "sharps" containers (Fig. 6-10).
   b. Proper use of a self-sheathing ("safe" needle) needle or syringe unit (as discussed in Chapter 5) minimizes risk of accidental needle stick.
   c. When needles are to be reused for subsequent injections (a unique feature of dentistry versus medicine, where second injections are rarely administered), recapping is accomplished using the "scoop" technique or a needle holder (Fig. 6-11).
   d. Contaminated needles should *never* be discarded into open trash containers.

In summary, only one local anesthetic needle is necessary in the dental office, the *25-gauge long*, which can be used for all the anesthetic techniques discussed in this book. It provides a rigidity, which is necessary in the periodontal ligament (PDL) and intraseptal injections, that is not available with higher-gauge (smaller-diameter) needles; it deflects to a lesser degree than smaller needles and seemingly provides easier and more reliable aspiration. Because there is no increase in patient discomfort with the 25-gauge

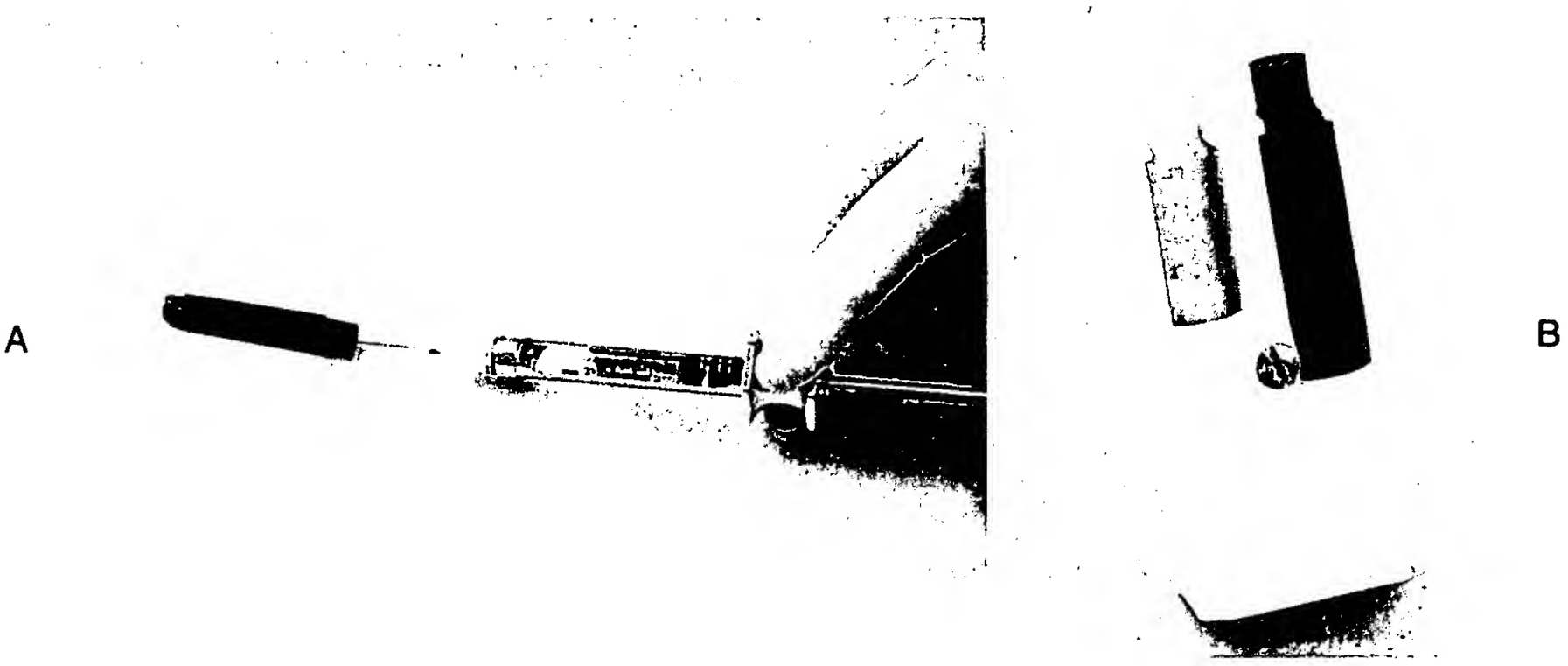

Figure 6-11. A, "Scoop" technique for recapping contaminated local anesthetic needle. **B,** Plastic needle cap holder.

long needle, its value is increased still further. In reality, however, it is practical to have a second needle available: The 25- or 27-gauge short needle is used for injection techniques in which the thickness of soft tissue to be penetrated is less than 20 mm and where the risk of positive aspiration is minimal, as well as in areas of the oral cavity where stabilization of a long needle might prove difficult (e.g., maxillary anterior teeth and the palate).

PROBLEMS

Pain on Insertion

The use of a dull needle can lead to pain on initial penetration of the mucosa. This pain may be prevented by using sharp, new, disposable needles and applying a topical anesthetic at the penetration site. The needle should be changed after three or four penetrations of mucosa if reinsertion is necessary.

Breakage

Bending weakens needles, making them more likely to break on subsequent contact with hard tissues, such as bone. Needles should not be bent if they are to be inserted into soft tissue to a depth of more than 5 mm. *There is no injection technique used in dentistry (in which the needle enters into soft tissue) that mandates that the needle be bent for the injection to be successful.* Most often needles are bent by doctors administering an inferior alveolar nerve block (IANB), a posterior superior alveolar (PSA) nerve block, an intrapulpal injection, an injection into the PDL, and the intraosseous injection. The two nerve blocks mentioned can be easily administered successfully with a

Figure 6-12. Retained broken needle after inferior alveolar nerve block *(arrow)*.

Figure 6-13. Remainder of retained local anesthetic needle shown in Figure 6-12.

straight (unbent) needle (see Chapters 13 and 14). The PDL and intrapulpal injections usually can be administered without bending the needle; however, occasions arise, such as at the distal root of a mandibular second molar (PDL), root canals in posterior teeth (intrapulpal), or injection into bone distal to a second molar (intraosseous), in which the injection site is not accessible with a straight needle. Bending of the needle is essential to success in these cases. Because the needle does not enter into soft tissue more than 2 to 4 mm (PDL), or at all (intrapulpal), there is little danger of the needle becoming nonretrievable in the unlikely event that it breaks (Figs. 6-12 and 6-13).

No attempt should be made to change the direction of a needle when it is embedded in tissue. If the direction of a needle must be changed, the needle should first be withdrawn almost completely from the tissue and then its direction altered. No attempts to force a needle against resistance should be made (needles are not designed to penetrate bone). Smaller (30- and 27-gauge) needles are more likely to break than larger (25-gauge) needles.

This author has been involved in 33 cases of broken needles that went into litigation (over a period of 30 years), and is aware of an additional 27 broken needle cases reported to manufacturers of the needles. In 59 of the 60 broken needle situations the needle involved was a 30-gauge short or ultrashort. A 27-gauge short needle was involved in the only other case.

Recommended needles for specific injection techniques are presented in the recommendations section that follows.

Pain on Withdrawal

Pain on withdrawal of the needle from tissue can be produced by "fishhook" barbs on the tip. Fishhook barbs may be produced during the manufacturing process, but it is much more likely that they develop when the needle tip forcefully contacts a hard surface, such as bone. A needle should never be forced against resistance. If in doubt about the presence of barbs, change the needle between insertions.

Injury to the Patient or Administrator

Penetration of, with injury resulting to, areas of the body with the needle can occur unintentionally. A major cause is carelessness and inattention by the administrator, although sudden unexpected movement by the patient is also a frequent cause. The needle should remain capped until it is to be used and should be made safe (sheathed or recapped) immediately after withdrawal from the mouth.

RECOMMENDATIONS

1. Sterile disposable needles should be used.
2. If multiple injections are to be administered, needles should be changed after three or four insertions in a single patient.

TABLE 6-5
Recommended Needles for Injection Techniques

Technique	Needle Gauge	Needle Length
Supraperiosteal (infiltration)	27	Short
Posterior superior alveolar nerve block	27*	Short*
Middle superior alveolar nerve block	27	Short
Anterior-middle superior alveolar nerve block (AMSA)	27	Short
Palatal approach (ASA)	30†	Ultrashort
Buccal (long) nerve block	27‡	Short‡
Infiltration for hemostasis	27	Short
Periodontal ligament injection (PDL or ILI)	27	Short
Intraseptal injection	27	Short
Intraosseous injection	27	Short
Intrapulpal injection	27	Short
Anterior superior alveolar nerve block ("infraorbital")	25	Long
Maxillary (V_2) nerve block	25	Long
Inferior alveolar ("mandibular") nerve block	25	Long
Gow-Gates mandibular nerve block	25	Long
Vazirani-Akinosi mandibular nerve block	25	Long

*In earlier editions of this book, the 25-gauge long needle was recommended. As a means of minimizing the risk of hematoma after the posterior superior alveolar injection, a short needle is now recommended. If available, a 25-gauge short needle should be used; where this is not available, the 27-gauge short needle is recommended. (See Chapter 13 for additional discussion.)

†The authors of the P-ASA paper recommend use of 30-gauge ultrashort needle.[17,18]

‡In most clinical situations the 25-gauge long needle, used for the IANB, is used for the buccal nerve block, which is administered immediately after the IANB.

3. Needles must *never* be used on more than one patient.
4. Needles should not be inserted into tissue to their hub unless it is absolutely necessary for success of the injection.
5. A needle's direction should not be changed while it is still in tissue.
6. A needle should never be forced against resistance.
7. Needles should remain capped until used and made safe immediately when withdrawn.
8. Needles should be discarded and destroyed after use to prevent injury or reuse by unauthorized persons.
9. The injection techniques in Table 6-5 are listed with their recommended needles (for the average-size adult).

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